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Title: Iterative co-design and testing of a novel dressing glove for Epidermolysis Bullosa

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Abstract

Background:

Recessive Dystrophic Epidermolysis Bullosa is a rare genetic skin disorder which requires intensive hand therapy to delay fusion of the digits. Existing dressings do not conform to the complex structure of the hand and are applied in patches held with additional bandages leading to an occlusive environment.

Objectives:

To co-design a dressing glove based on user experiences and needs.

Methods:

Qualitative interviews and focus groups with children and adults with Recessive Dystrophic Epidermolysis Bullosa and their carers were conducted. Iterative feedback of design cues, bench and surrogate testing of materials and prototype refinement were achieved through collaborative co-design with patients, carers, clinicians and manufacturers.

Results:

Thematic analysis generated eight user needs and corresponding design cues addressing issues of absorbency, adherence, comfort, adaptability, ease of application and removal, breathability, protection, and hand hygiene. One prototype was selected for proof of concept testing.

Conclusion:

This novel dressing glove design meets the patient's requirements of a dressing, which conforms to the structure of the hand and sits into the web spaces to keep fingers separated. Proof of concept testing has since been undertaken with patients to determine performance, value for money and whether further developments are required and will be published in a separate paper.

Introduction

Wound care is a pivotal component of the management of Epidermolysis Bullosa (EB). In severe forms of EB including Recessive Dystrophic EB (RDEB) skin blisters and tears at the slightest touch, resulting in webbing of the digits, painful wounding and scarring.^{3,7,8}

Blisters are not self-limiting and will continue to enlarge unless punctured with a sterile needle and drained. Hands and feet are particularly exposed to trauma having a significant impact on function, quality of life^{7,9} and independence (Image 1). Current hand modalities include wound dressings and bandages wrapped around fingers, web-spacer gloves worn over dressings to delay webbing, thermoplastic and putty splints to delay contractures.¹² (Box 1).

The most appropriate dressing type depends on an individual's EB subtype, the characteristics and location of the wound.¹³⁻¹⁷ EB patients need dressings that are non-adherent, semi-permeable and absorbent.¹⁵ Dressing use is also determined by patients' preferences and practitioner experience^{15,24,25} however dressing changes are often painful and time consuming.^{15,26-28} While existing dressings meet many of the desirable features for EB none conform to the complex structure of the hand and have to be applied in patches. This requires additional bandages to hold dressings in place around the hand and between the web spaces (Image 2).

This project is based on feedback from; (a) a patient in a previous study,²⁹ who observed that the Skinnies WEB™ web-spacer gloves could extend the period between re-webbing and repeat surgery attributed to how well they sit into the web spaces³¹ and (b) a patient who always wears gloves over his dressings to prevent finger webbing. Following these observations we were tasked with developing a dressing in the form of a glove so that

desirable characteristics of the glove structure could be integrated with the function of a dressing: a 'dressing glove'. The dressing glove also needs to be compatible with the Skinnies WEB™ web-spacer glove, which is worn over the top of the dressing glove to ensure there is pressure on the web spaces to prevent finger webbing and also acts as a dressing retention garment (<http://www.skinniesuk.com/product/630/WEB-Full-5-Digit-Gloves>).

We adopted a model of user engagement to inform the device development process.^{2,6,22}

Our first aim was to understand user experiences and needs relating to hand dressings for RDEB and gauge support for the use of a glove design. Our second aim was to translate these experiences and needs into design cues and develop a prototype of the dressing glove in preparation for proof-of-concept testing (Stages 1 and 2 in Box 2). This study is part of a larger project (GLOVE: Generation and evaluation Of hand therapy devices for Epidermolysis bullosa) encompassing six interrelated work packages based on a framework for medical device development for hand therapy, and evaluation (Box 2). Stages 3, 4 and 5 will be published in due course.



Image 1: Adult with RDEB with no dressings



Image 2: Same adult's hands (from Image 1) with Metipel and Polymem dressings under bandages. This individual also wore black wool gloves over his dressed and bandaged hands to maintain his web spaces.

Box 1: Epidermolysis Bullosa Clinical Profile

- Epidermolysis Bullosa (EB) is a group of genetic conditions causing extensive, painful skin blisters and wounds.³⁻⁵
- It occurs in approximately 1 in every 17000 live births and there are currently 5,000 affected individuals in the UK (www.debra.org.uk).
- Whilst over 30 variant forms of the disease exist, 4 main sub-types of EB are recognised, based on whether the mutated protein is located in the epidermis, dermal-epidermal interface or in the dermis. These are Epidermolysis Bullosa: EB Simplex, Dystrophic EB, Junctional EB and Kindler Syndrome which present with increasing severity¹⁸
- As well as compromised epithelia and mucosae, affecting digestive, respiratory and ocular systems^{3,4,7}, joint contractures develop that can require several surgical interventions to release them.^{19,20}
- All types of EB affect the hands but those usually requiring hand surgery and therapy interventions have Recessive Dystrophic EB (RDEB)
- Hands may be normal at birth but are soon subjected to a destructive cycle.¹³
- EB hands are small due to contractures.^{4,13}
- Wound healing is challenging and is adversely affected by malnutrition, anaemia, infection and pruritus.^{5,7,14,24}
- Both hands are affected irrespective of hand dominance and clinical experience shows that contractures differ in each hand.^{12,14}
- Repeat blistering results in skin breakdown and healing with scar tissue, which leads to finger webbing and contractures of the hands, which can require surgical interventions to release.^{19,30}
- Following surgery, hand therapy interventions are essential to maintain and regain movement and try to delay inevitable recurrences.^{17,32}

Box 2: Stages in medical device development and evaluation

Stage 1: Understanding user experiences and needs ^{1,2}

Stage 2: Translating user needs into prototype development ^{2,6}

Stage 3: Testing the effectiveness of the medical device adopting an n-of-1 methodology ^{10,11}

Stage 4: A model of economic evaluation ²¹

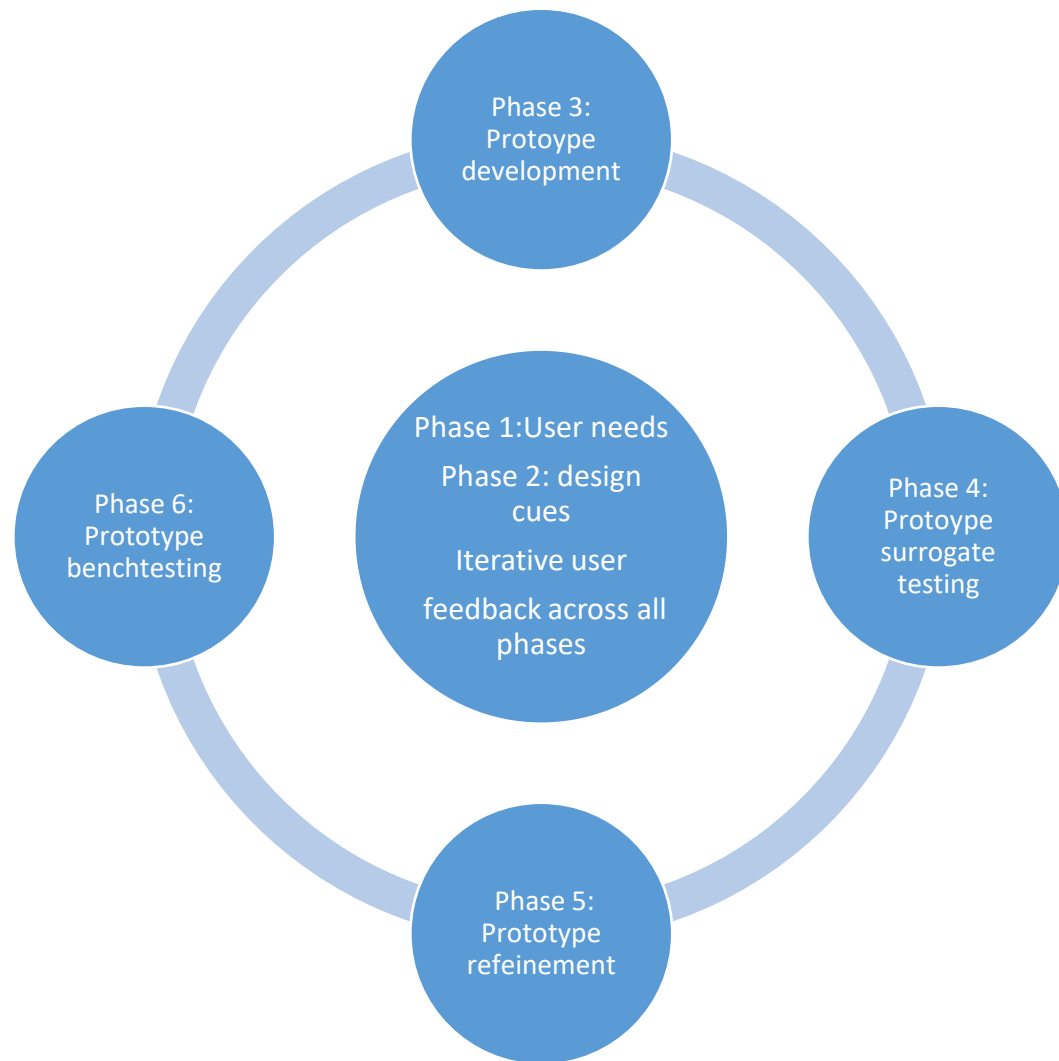
Stage 5: Longitudinal assessment of devices in routine practice via implementation of data capture tools ^{22,23}

Methods

Study Design

We adopted a co-design methodology involving interviews and focus groups with a purposive sample of children and adults with RDEB (Table 1), their parents and carers; bench and surrogate testing of materials and prototypes of the dressing glove; iterative feedback and prototype refinement through collaborative co-design (Figure 1) aligning design and manufacturing with the user needs. ^{23,33}

Figure 1: Iterative development of prototypes through co-design, bench and surrogate testing



Ethical approval

The project was given ethical approval by the London Bridge Research Ethics Committee (Ref 14/LO/0802). Informed consent was obtained from each patient. For children, parental consent was sought from parents before consent was obtained from the children themselves. Children aged under 6 gave assent following their parent's consent for them to take part in the study.

Phase 1: User needs and experiences

Qualitative data collection took place at two UK National Centres for EB between October 2014 and May 2015. The specialist occupational therapists and clinical nurse specialists caring for individuals with RDEB invited children, adults and their carers to take part by letter. Individuals with RDEB were selected because they experience the most severe hand deformities and require extensive hand therapy.

Both focus groups with children and parents were facilitated by two of the authors and attended by the inviting clinicians. Adult patients were delayed by other appointments when we planned to conduct focus groups so individual interviews were completed. All but one interview was conducted by one of the authors and the occupational therapist treating the patients.

EB patients and carers are experts in their condition²⁴ and have developed respectful and enduring relationships with the clinical teams that care for them. As such we felt that participants would welcome being able to discuss their experiences of treatment with the clinicians present. Encouraging this collaborative dialogue was also an integral part of the co-design process to ensure shared understanding of experiences of hand therapy and treatment goals.³³

The focus groups and interviews were conducted using a topic guide (Appendix 1), which was developed in consultation with patients and clinicians. Each focus group and

interview was audio recorded and transcribed verbatim by one of the authors. The transcripts were edited for accuracy by three authors and supplemented with field notes taken during data collection. All participants over the age of six provided informed consent. Children aged four to six provided informed assent and their parents provided consent.

Phase 2: User needs and experiences interpreted through thematic analysis of focus group and interview data

We undertook an inductive thematic analysis³⁴ framed by an interpretivist approach³⁵ which aims to ensure the findings were grounded in the experiences of people living with RDEB. We adopted a team analysis approach, which added to the rigor of the study as we challenged each other to explain our interpretations of the data.³⁶

Transcripts were read through by all the authors and a series of codes identified by three authors. Similar codes were grouped to form themes categorising patient and carer's experiences. Each theme was scrutinised to ensure the data were mutually exclusive and consistent within each one. The themes were then translated into design cues: desirable attributes of a dressing that would counteract the negative experiences and meet the requirements described by patients and carers.^{2,6} Patient and carers reviewed and endorsed the themes and their corresponding design cues (respondent validation^{37,38}). Data collection and analysis continued until no new themes or design cues emerged.³⁵ The purpose of the analysis was not to generate theory but to inform the co-design of the new device.

Phase 3 and 5: Prototype development and refinement

The user needs and design cues were presented to two manufacturers, a clothing designer, patients, carers and clinicians at a series of meetings held at both clinical sites and at a University location. User feedback also included one-to-one discussions on the design and function of the dressing glove providing further validation of the design cues and prototype features (see box 3 below). Manufacturers and the research team identified viscose and elastane as suitable yarns, woven into a glove using seamless knitting technology (<http://www.seamlessknitwear.com/about/about-us.php>). Another possibility was a specially-engineered breathable polyester fibre, used in sportswear (Coolmax™). Through an iterative process of surrogate and bench testing (see phase 4 and 6 below), user feedback and refinement one prototype was chosen to go through to proof-of-concept tests with patients (Image 3 and 4).

Box 3: Prototype dressing glove project meeting notes vignette

Patient 1 queried whether the glove would replace Polymem™ (Aspen Medical Limited). The researcher asked why he needed Polymem™. The explanation was that his wounds tend to be 'mucky'. The researcher made the suggestion that this may arise with infrequent dressing changes (three to four days), because currently these are unpleasant and painful – an observation made by the patient in previous interview. Patient 1 agreed. The researcher noted that current dressing systems make the skin and wounds over moist, encouraging bacteria to colonise. With the new dressing glove, the absorptive/wicking function and ability to change gloves frequently and without trauma, blisters should not give rise to 'mucky' wounds.

Both Patient 1 and Patient 2 indicated their interest in the new dressing glove concept. Patient 1 asked for full finger designs. Patient 1 said how important it is to have gloves that fit the fingers without hanging off the tips because they are too long. Patient 2 favoured fingerless and with long cuffs to support vulnerable areas on her forearms. The need for bespoke designs for some patients was confirmed.

Patient 1 asked for further information on the purpose of the dressing glove and using it on areas on the hand where there are no wounds. The researcher agreed that these issues have to be factored into the design of the dressing glove. The dressing glove can also be taken off by the patient even if only one wound is causing an issue. Patient 2 asked if it would be possible to check the skin underneath the dressing glove? Would the glove be transparent? Researcher said the dressing glove will be made of stretchy material and so it would be possible to see if a blister is developing. The researcher suggested patients/carers roll back the glove, lance the blister and roll back the dressing glove into place (see clinical protocol Appendix 2). It will be up to the patients as to the number of times they would want to take the dressing glove off.

Phase 4 and 6: Prototype bench and surrogate testing

The selected viscose dressing material was tested for absorbency and fluid retention by Speciality Fibres and Materials Limited, using three different test solutions for each test; solution A (calcium-sodium solution); serum solution (90% solution A/10% foetal calf serum); physiological solution (0.225% sodium chloride, 5% glucose, in deionised water). The Surgical Material Testing Laboratory, Wales (SMTL) performed adherence tests on prototypes, comparing performance to commercially available comparator silicone coated dressings; Mepitel; NA Ultra. Surrogate tests were conducted by all authors assessing: glove comfort (tactile feel when dry and upon experimental blister popping/re-drying conditions), heat generation as well as ease of application and removal (upon submerging in water); glove fit and ability to use a touch screen device. Surrogate tests were also performed on prototypes (V1 and S1) when worn together with the web-spacer glove.

Results

Phases 1 and 2: User needs and design cues

Two focus groups were conducted with six children and their parents and individual interviews were held with seven adults (Table 1). Eight interrelated user experience themes and corresponding design cues guided the development of the novel dressing glove, aimed at addressing issues of absorbency, adherence, comfort, adaptability, ease of application and removal, breathability, protection, and hand hygiene (Table 2).

Table 1: Patient characteristics, recruitment and data collection

Data collection method/Sample characteristics	Focus group 1	Focus group 2	Individual interviews
Number of individuals with RDEB	2	4	7
Number of Parents/carers	5	6	3 ¹
Total number of participants	7	10	10
Age range of individuals with RDEB	4-7 years	under 4 years	25-75 years
Gender of individuals with RDEB	1 male and 1 female	3 male and 1 female	3 males and 4 females

¹ These carers accompanied their adult children to their interviews.

Skin trauma associated with wearing and changing dressings: the need for non-adhesive/low adherent dressings

Patients and carers associated current dressing materials with dryness, being too ridged and sticking to the wound, which led to lengthy painful removal and sore skin (Q1). Dressing changes varied from half an hour to an hour often involving dressings being soaked to aid removal, particularly post operatively. The anticipated pain associated with dressing changes led one participant to limit his dressing changes to every other day.

Adult: Well, it's not really good, I feel because I have some sore areas so every time I have to change my dressings on my hands, I'm really reluctant so I try to avoid it every time. But I have to do it so it's a long and painful experience because of sore areas on top and the skin is very sensitive (Interview 2)

The user experiences illustrated the importance of minimising adherence between the dressing material and the skin. Some adult patients and parents noted that dressings would often crease resulting in rubbing and then blistering. One parent described how blisters would occur at the edge of a wound if the adhesive tape was positioned in the wrong place and if the dressings were too big. Two parents noted that blisters would appear when they wrapped dressings around their child's fingers; a practice used to maintain web spaces.

Difficulties of the dressing change: need for dressings that are easy to remove and put on

Dressing changes were described as 'challenging' and participants noted it was awkward to apply dressings between the fingers, particularly where fingers have webbed or started to fuse (Q2). Holding dressings in place on the hands whilst putting on bandages and keeping all the materials in place with tape was also a difficult task. Adults and parents customised their approach when applying and changing dressings. Two participants valued the concept

of a dressing that could be slipped on rather than having to wrap dressings around the fingers to minimize skin trauma.

Parent: I just do it [cut dressings] by eye now because you do it that often literally so (laughs when she says this); you know sort of roughly know what size and that to do it. (Focus Group 1)

Dressing limitations and failure: importance of comfortable, adaptable materials that are breathable

Adults and parents described dressings as ‘baggy’, ‘bulky’ and ‘hot and sweaty’. Parents noted particular dressings tore easily during dressing changes. Participants described how dressings and retention garments could limit hand function (Q3) restricting everyday tasks such as holding a pen and toileting. Dressings were associated with wearing layers of materials, creating a mitten-like effect (Q4). Many of the participants had experience wearing the Skinnies Web TM gloves (dressing retention garment) and noted that the material was breathable:

Adult patient: I find it quite difficult to dress the hand and then still use it, so if the hand is quite padded, I'm not going to be able to use it anyway and then sometimes, like with the Skinnies garments, it's nice when the air can sort of circulate. Sometimes I find it helps with healing anyway... I suppose mainly because it's difficult to dress the hand, I find. (Interview 6)

Skin breakdown and the importance of managing blister fluid and exudate

Participants described the different ways that Recessive Dystrophic Epidermolysis Bullosa (RDEB) affects their hands. A common experience was blisters on hands and fingertips.

One adult patient noted that blisters could spread on the hands with the amount of blister fluid ranging from a teaspoon to tablespoons. Blisters were also associated with the rapid development of webbing and contractures (Q6) and the loss of nails, toes and fingers at a young age. One parent described how blisters would appear on their child's hand after he had touched something when not wearing gloves. A phenomenon particular to children with RDEB was described as 'de-gloving', when the skin on the entire hand is 'pulled off' when holding hands with an adult. Common to both adult patients and children was severe itching and continual scratching especially at night time contributing to a continuous cycle of skin damage. One carer expressed his support for the dressing glove concept to manage blister fluid;

Adult patient: So it keeps them apart doesn't it? Cos that's one of the things, if you've got blisters and you've got to bind them, you've still got to dress them separate; you can't let them stick together...so you've got to make sure that you, you know keep them open which then it gets very bulky for your finger

Patient's husband: Which is why the glove is such an improvement, cos you can dress between the fingers and put the glove onto it and its holds the wound apart

(Interview 1)

Value of wearing dressings and gloves: protect skin and maintain web spaces

Although dressings were associated with skin trauma, some adults and parents observed how particular types of dressing (e.g. Vaseline gauze) enabled use of the hands for tasks during the day thereby providing a protective layer for the skin (Q7). Finger wrapping was also noted as a protective strategy to stop children's finger web spaces becoming fused. One adult felt very strongly about wearing (standard wool) gloves over his dressings throughout the day, because it helped to keep his web spaces separate and skin in relatively good condition:

Adult: 'No because they protect me quite a lot to keep the separation of the fingers, Yeah. I mean I was using, I use the dressings so if you want to see you. (shows his hands under the gloves)...so I use the Vaseline gauze in the middle of the fingers to separate them but now I am wearing the (wool) gloves, I don't really need to because the work is done.' (Interview 2)

Importance of infection control: antimicrobial element

Adult participants noted that infection control was an important element of a dressing and some referred to co-existing skin problems. One adult explained that once a wound was infected it would get larger and that this was difficult to control (Q8). Another adult noted the heat generated by dressings often made it difficult to stop infections occurring.

Carer: 'The most difficult bit/ area containing infection with (name of patient) now having lupus, we try not to use antibiotic if we don't have to, and the only cream which is effective is hydroperoxide...so a dressing that incorporated some antibacterial material or had an antibacterial element in it to contain infection would be an absolute godsend' (Interview 3)

Table 2: Translation of user needs to prototype dressing glove

User experience theme	Illustrative quote (Q)	Design cue	Prototype Version 3 (final)
Skin trauma associated with wearing and changing dressings	<p><i>(Q1) Researcher: Did you say you tried it (finger wrapping) with (name of child) but it did not work?</i></p> <p><i>Parent 1: We tried it once but it made his fingers blister. We spent an hour.</i></p> <p><i>Parent 2: Yeah, you can spend like two hours, it's so hard to do, if you get one crease and it rolls up and you have to be so careful don't you with EB.</i></p> <p><i>Parent 1: Also if it does blister, then it is going to stick as well.</i></p> <p>(Focus Group 1)</p>	Low adherence	Silicone layer for low adherence (concentration increased to 5%)
Difficulties of the dressing change	<p><i>(Q2) Yeah, I think it was about 20 minutes when we were doing it. We were doing it obviously slowly and trying to make sure they were right in the web spacers and getting them to fit the fingers and making sure all the bits were cut... no within the whole thing; I timed it and it took me about an hour... because it gets stuck...and that's what slows you down and that's what sort of, the painful bit. (Interview 6)</i></p>	Easy to remove and put on	Stretchy material for ease of application and removal
Dressing limitations and failure: Bulky, baggy/unstable	<p><i>(Q3) Researcher: Is there a reason you wouldn't dress the blisters?</i></p> <p><i>Adult: because I find it quite difficult to dress the hand and then still use it (Interview 6)</i></p>	Comfortable 'dressing glove' design	Stretchy material is comfortable Seamless knitted glove structure

User experience theme	Illustrative quote (Q)	Design cue	Prototype Version 3 (final)
<p>Dressing limitations and failure:</p> <p>Inflexible/non-adaptable</p>	<p><i>(Q4) Carer: I have used the gloves [Skinnies WEB™] and they are brilliant but I've used the gloves and you can just put the bit between the finger and it stays there but the tubular bandage you could not get it between the fingers. So, you've lost the use of the fingers because of the tubular bandage twisting back down and over it</i></p> <p><i>Adult: Like a mitten</i></p> <p><i>Carer: So it was like a mitten when you actually finished the dressing but with that [Skinnies WEB™] (name of Adult) has got full use of her hand and as she has to do all the driving at the moment, it's brilliant. (Interview 1)</i></p>	Adaptable	<p>Stretchy material is adaptable</p> <p>Seamless knitted glove structure</p>
<p>Dressing limitations and failure: Hot and sweaty</p>	<p><i>(Q5) Yeah, because if I've got a dressing on, that there, the skin there, it would sweat more and then break down again, so I'm back to square one after getting it healed</i></p> <p><i>(Interview 4)</i></p>	Cool/breathable	Evaporation of heat/moisture
<p>Skin breakdown (blistering and webbing) and the importance of managing blister fluid and exudate</p>	<p><i>(Q6) Adult: 'I had one big blister right in the creases of three fingers at the base and it drew in within 24 hours. It was an absolute nightmare; I'd kept it straight for so long but this one blister was massive and it took two or three fingers at the base. Forty-eight hours and my hand creased in as it is now; it's a pain'. (Interview 7)</i></p>	Absorbent	Medium absorbency

User experience theme	Illustrative quote (Q)	Design cue	Prototype Version 3 (final)
Value of wearing dressings and gloves: to protect skin and maintain web spaces	<i>(Q7) Mother: Yeah because if she did not have any wounds on the hands at all now and I left that [dressings] off, she would probably would get blisters and then throughout the day she would not be able to do as much she wanted to do throughout the day so she definitely like, if she pushes herself up and that, she would probably get blisters here or on her wrists – wouldn't you? (question directed to her child) just anything really. It does save like blistering and reduce it on her hands by having it [dressings] on so she wears it like 24/7 really. (Focus Group 2)</i>	Spacing between fingers: support for a 'dressing glove' design	Knitted 'glove' structure
Importance of infection control	<i>(Q8) But if it's infected it is hard to control and the wound gets larger as the infection gets a grip on it, so a means of controlling the infections would be, it helps the healing, the healing is so much quicker if you have control of the infection (Interview 3)</i>	Antimicrobial element	Antimicrobial finish

Phase 3, 4, 5 and 6 results: Prototype development, bench and surrogate testing and refinement

Four prototypes (S1, V1, V2, V3) were iteratively developed from the design cues, testing, feedback and refinement (See Figure 2 and Table 3 for details). The prototypes were treated with silicone (Tubingal HWS, final concentration 3%) to reduce adherence and an antibacterial (Sanitized T 99-19, final concentration 1.5%) to prevent bacterial growth within the knitted fabric. After the first surrogate tests (Box 5), we agreed the most appropriate concept would be V1 due to higher absorbency and softness. To improve fit and add ‘ping’ to V1 an increased percentage of Elastane in the yarn was suggested (V2). Due to both the elasticity of the dressing glove material (V2) and the delamination of Mepilex, SMTL found it challenging to test them for adherence. SMTL concluded that compared with Mepilex Transfer, the dressing glove material was more adherent but as the method is a quality control method rather than a clinical simulation, it was not possible to equate the results with a clinical outcome (see SMTL report Appendix 3). When the dressing glove was compared to NA Ultra™, the latter dragged on the skin with the potential for causing wrinkling of the skin and friction damage. To reduce adherence the percentage of silicone concentration for the dressing glove was increased to 5% (V3 Image 3). Dressing glove V3 performed as well as V1 in the surrogate tests however the gloves still had the potential to “drag” over the hand so a clinical protocol, agreed with the clinicians and patients was developed for glove application and removal (see clinical protocol Appendix 2).

Box 4: Results of V1 surrogate tests

Viscose (V1) gloves felt more soft and comfortable against the skin than S1 although no excessive heat was perceived for either. For V1, fluid was efficiently absorbed within a small area of the glove which dried out in 30-40 minutes, without affecting the feel of the fabric. Following submersion in water, the V1 gloves became slack, easing removal. S1 gloves did not slacken, raising concerns that removal would be difficult. Researchers were still able to use touch screen devices with V1 and S1. The main drawback to V1 was lack of conformability against hands/wrist which could potentially crease or sag. For S1 fit was good, due to high stretch capacity of the material, however the gloves “pulled/dragged over the skin” when put on. S1 absorbed fluid, though not to the same extent as V1, raising concerns that lower absorbance may lead to fluid leaking.

When Skinnies Web™ Spacer gloves were worn on top of both S1 and V1 dressing gloves, no significant changes were reported in term of comfort in dry/blister popping/re-drying conditions and heat generation. Skinnies Web Spacer™ glove improved the fit of the dressing gloves around the wrist and increased the force applied between the fingers, improving web spacing capacity.

Table 3: Results of Absorbency and Retention Test for Dressing Glove V3

	Absorbency (g/100cm ³)	Retention (g/g)
Dressing glove in solution A	11.40 ± 0.57	1.25 ± 0.06
Dressing glove in serum solution	11.60 ± 0.58	1.25 ± 0.06
Dressing glove in physiological solution	10.87 ± 0.54	1.26 ± 0.06

Figure 2: Iterative development and refinement of prototypes through bench and surrogate testing with results

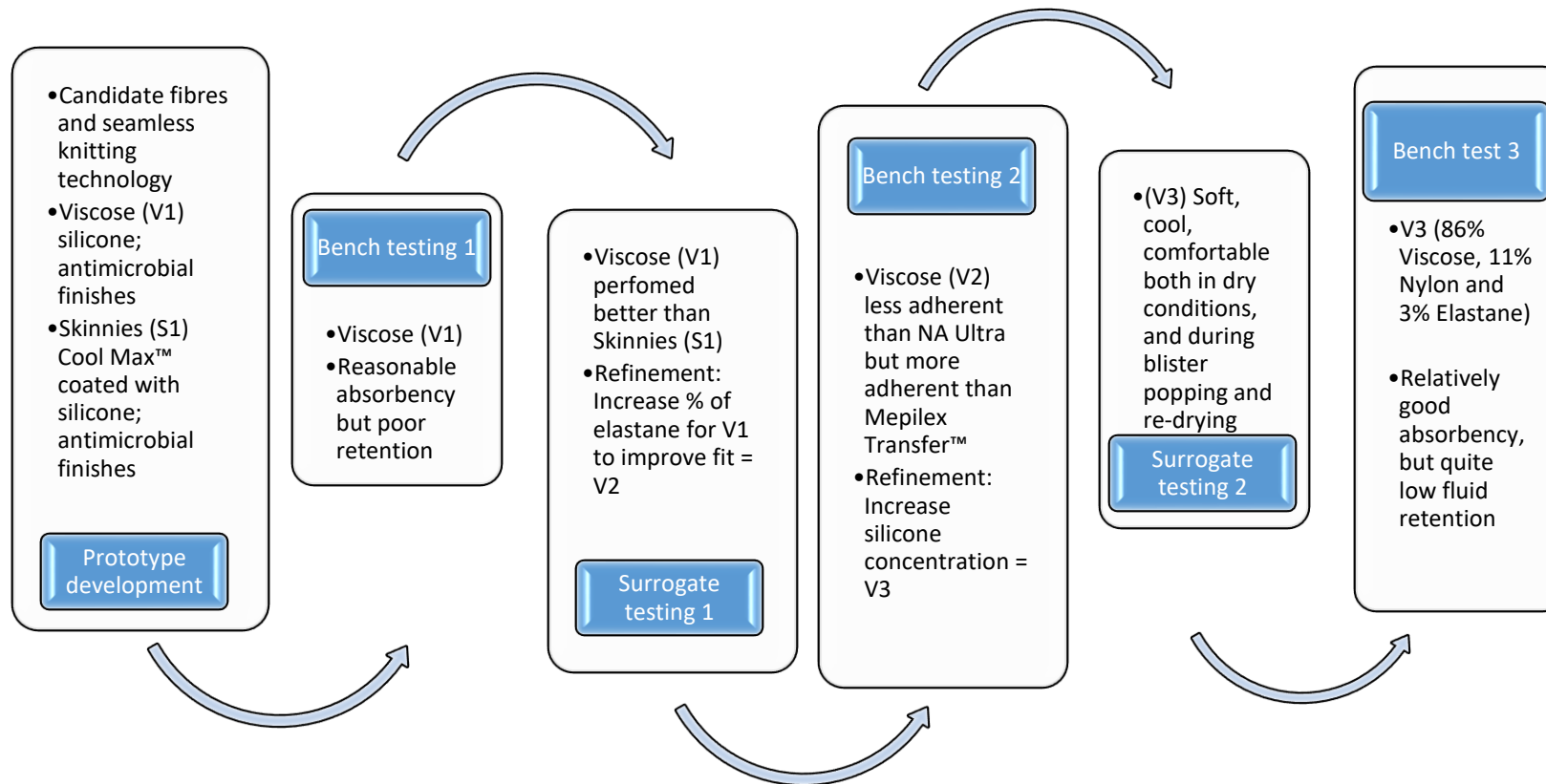




Image 3: Same adult from images 1 and 2 (right hand) in the dressing glove. The emollient applied began to strike through but was contained once the Skinnies web spacer glove was worn over the top (see below).



Image 4: Same adult's left hand wearing the dressing glove and the Skinnies web spacer glove (over the top of the dressing glove)

Discussion

A prototype dressing glove for RDEB was co-designed with patients, carers, clinicians, clothing designers and dressing and glove manufacturers following a model of user engagement. Eight user experience themes and corresponding design cues were translated through thematic analysis and iterative feedback. Bench and surrogate testing provided information about the safety and quality of the dressing glove and guided iterative refinements.

EB wound care guidelines acknowledge that dressings can be difficult to fit and keep in situ.^{39,40} We have started with a design that fits the hand – a seamless knitted glove, which incorporates discrete and basic functions of a wound dressing for EB hands.¹⁵ The dressing glove has been CE marked as a Class I medical device. It is non-sterile and an antimicrobial finish has been added to suppress the growth of organisms and odour generation. The seamless function supports conformability to the hand reducing the need for multiple layers to hold dressings in place which can cause wrinkles or creases and generate further blisters. Surrogate testing showed the dressing glove was compatible with the Skinnies web-spacer glove which also acts as a dressing retention garment if needed. The Skinnies web-spacer glove has also undergone refinements during the study to improve fit and performance. This will be reported on further in the proof-of-concept study publication. The dressing glove can be either standard sizes or for more contracted hands as occurs with RDEB patients, can be bespoke manufactured according to measurements taken by hand therapists enhancing fit and comfort. In addition to functioning as a dressing, the glove design can support the maintenance of web spaces either on its own or when worn under the Skinnies web-spacer glove, which is important before and after surgery [unpublished observations].⁴¹

Trauma to the skin associated with dressing use, reported in this study, is consistent with previous studies and clinical guidance reporting treatment-related pain attributed to dressing changes^{15,26} dressing adhesion to skin and blister formation associated with dressing use.^{15,28,39,42} The finding that dressing changes are time consuming is also supported by earlier evidence.^{27,28} This is the first qualitative study of the experiences of dressings on the hands for people with RDEB. Our study adds further detail about why dressing use on the hands is problematic and changes are often avoided: adults and parents report dressings can limit hand function, often do not stay in place, can be hot and sweaty and are awkward to apply.

The dressing glove has stretch and recovery for ease of application and removal. The knitted structure also slackens when wet, enabling atraumatic removal when patients immerse their hands in water. If these design cues stand, dressing changes should be less traumatic and enable more frequent (daily) dressing changes, a more hygienic option than dressings in situ for days. Low fluid retention, observed during the testing phases, could be an advantage clinically, ensuring the dressing glove evaporates the water content of absorbed blister fluid. Whilst the dressing glove material drying time was not measured precisely, surrogate testing put this at around 30-45 minutes for the dressing glove. We therefore envisage diminished maceration of the skin, which is present when hands have been covered in layers of semi-occlusive dressings for 2-4 days.^{43,44} Reduced maceration may optimise skin strength and resistance to bacterial colonisation and infection.⁴⁵

This study focused on a rare genetic skin condition. As a result our findings are specific to a particular group, RDEB, and are not necessarily representative of the wider population. However, managing fragile skin, blisters and wound care resonates with a broad range of conditions requiring wound dressings on the hands and compression to manage scar tissue,

for example burns. RDEB is a debilitating and onerous condition which requires patients and carers to attend a large number of appointments. As data collection took place in clinic, we were unable to employ more age appropriate methods such as drawing and game playing which require more time and opted to interview children and young people together with their parents.

Wound management and in particular maintaining web spaces is pivotal to long term outcomes [unpublished observations].¹⁵ Hand dressings for EB have not been developed based on user requirements and experiences of hand therapy. We hypothesise that if the development of hand therapy devices is guided by a model of user engagement ^{2,6} we may be able to produce a dressing that meets user needs and by doing so improve user engagement with dressings and facilitate web space maintenance.

Our next step is to conduct a proof-of-concept study to evaluate the performance of the dressing glove prototype through patient and clinician recorded outcome measures of hand skin condition, hand function and experiences of wearing and changing dressings.⁴² We will also research the value-for-money proposition to the NHS of supplying the dressing glove. The proof-of-concept study will determine whether the dressing glove is 'fit for purpose' for frequent use for EB or whether further functions are required to be built into the device.

Other

We would like to thank the adults, children with RDEB and their carers for taking part in the study and the clinical teams looking after them. This article has also been reviewed and approved by two adult patients with RDEB.

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This project was conducted in collaboration with in kind non-monetary contributions from two manufactures; Speciality Fibres and Materials Limited and Skinwear Limited – representing a way of aligning research involving patients with industry.

Clothing designers involved in the early stages of the project were Conchita Currie and Alex Currie from CLC Design Consultancy Limited.

Conflict of interest

King's College London licensed the manufacturing of the Skinnies WEB™ garments to Skinwear Limited and receives royalties.

Appendix 1: Topic guide

In this session we would like to discuss your experiences of caring for your hands, and the devices you use. We have been told by patients that a glove design would work well for dressing EB hands. We will use the information you provide to design a 'dressing glove' to replace current dressings. We will invite you to review the prototypes later on in the project.

- 1) Please can you describe how you/your child's dressings are changed and applied?
What type of dressings do you use?
- 2) How long does a dressing change for the hands take?
- 3) How often are your/your child's hand dressings changed?
- 4) How do dressings affect the use of your hands?
- 5) Can you describe dressing change after you had an operation?
- 6) If you do not wear dressings, why? If you do not wear dressing how do you manage your blisters or wounds when they occur? How do you protect your hands when you get blisters?
- 7) Do you wear gloves on your hands? What type?
- 8) Does glove use affect the number of times you need to change your dressings?
- 9) How do you manage your/your child's web spaces? If you don't yet would you consider using anything for the web spaces?
- 10) How can current wound dressings and the Skinnies WEB (spacer?) glove be improved? Prompt: do you have any thoughts on new designs for wound management or maintaining web spaces?

Appendix 2: Protocol for Application and Removal of the Dressing Glove

V2 10 Jan 2017

1. Wash your hands with a hand wash of your choice and air dry
2. Apply an emollient of your choice to your hands
3. You or your carer should remove the glove from the packaging. Roll the right or left dressing Glove inside out like a 'doughnut', then ease the tips of your fingers into the glove and gently roll it down over your fingers, hand, wrist and forearm
4. While wearing the glove if you feel a blister developing, you or your carer should gently peel back the glove, pierce the blister as you do normally and drain the fluid into a pad, keeping the roof of the blister to act as a primary dressing. Re-position the glove. Should you decide to pierce the blister through the glove, do so and the glove will absorb the fluid and within 30 minutes will dry, leaving the texture of the glove unchanged
5. We recommend you change the dressing gloves daily and more frequently if you feel the glove has become grubby with wear in order to maintain hand hygiene.
6. To remove the gloves simply immerse your hand in a basin of water. The knitted fabric will slacken and enable you or your carer to slide your hand out of the glove. Dispose of the glove as you do normally with your dressings. If the glove has become stuck in any areas use Appeal™ or Prontosan™ to gently remove as you would with any other dressing that sticks.
7. Repeat Steps 1-3 to put on a new glove.
8. If you have any questions or comments about using the glove you can contact your hand therapist, the research team and EB nurse.
9. If you were to experience any adverse reactions to your hands while wearing the gloves please contact your hand therapist on (contact details removed); a member of the research team on (contact details removed) and an EB nurse immediately.

Appendix 3: Surgical Material Testing Laboratory Report

S. M. T. L.

Cover Sheet for Test Report

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Title: **Wound Dressing Adherency Testing**

Date: **As per approval signature at end.**

Other Keywords:

Report No: **16/5252/1**

Author(s)
Paul Fram

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Pages Text: 6	Other: 0	Total: 6	
No. Figures: 0	No. Tables: 3	No. Refs.: 0	

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3. Test Product(s)/Sample(s)

TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

Manufacturer	Item	Cat No	Batch/Lot No	Quantity	Date Received	SMTL Sample I.D.
Molnlycke Health Care	Mepilex Transfer Soft Silicone Transfer Dressing	294700	15273615	5	21-09-2016	50450
Molnlycke Health Care	Mepilex Transfer Soft Silicone Transfer Dressing	294700	16173615	5	21-09-2016	50451
Skinwear Limited	Viscose/Elastane Swatches (White)	Not Supplied (N/S)	N/S	10	15-09-2016	50241

NOTE: The test results in this report relate only to the test sample(s) analysed.

3.1 Departures/Abnormalities of Sample Condition

None.

4. Date of Testing

20th -21st October 2016

5. Testing Details

The adherency of the dressings were determined using SMTL test method TM-323.⁽¹⁾

In this test, a 2.5cm wide strip of non-woven swab is immersed in a solution of 30% gelatine then laid on the face of a 5cm wide length of the dressing under examination and covered with an acetate sheet. A load of 500g is then applied to the surface of the sheet and the gelatine allowed to set for 4 hours \pm 10 minutes.

After setting, the strip of non-woven swab is peeled from the face of the dressing using a constant rate of traverse machine and the peel force recorded.

5.1 Testing conditions

Conditioning and testing were carried out at $20 \pm 2^{\circ}\text{C}$ and $65 \pm 10\%$ R.H.

5.2 Deviations/exclusions from, and additions to standard methods.

Due to the elastic properties of the two materials that were submitted for testing, in order to stop the test material stretching and 'necking', the material was backed with a strong reinforced adhesive tape (Gorilla Brand).

5.3 Sampling Details

All samples were selected and supplied by the client.

5.4 Sample Preparation

As per the relevant SMTL Test Method.

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6. Results

6.1 Skinwear Coated Fabric Material

The adherency testing results of the coated fabric material is shown in Table 2 in which the force required to separate the non-woven fabric from the surface of the material under test are presented.

TABLE 2. Adherency - White Viscose/Elastane Swatches SID 50241

Dressing Type	Sample Number	Average peeling strength (N)	Average peeling strength (N/mm)
White Viscose/Elastane	1	5.1513	0.2061
	2	3.9567	0.1583
	3	4.7762	0.1910
	4	6.0991	0.2440
	5	5.5946	0.2238
Mean		5.1156	0.2046
S.D.		0.815	0.033

6.2 Molnlycke Mepilex Transfer

Attempts to test the Mepilex Transfer Wound Contact Layer utilising this test method were only partially successful. This was due to the non-woven test material and the contact layer separating so easily as to trigger the stop mechanism on the tensometer before any results could be obtained for two of the samples upon which testing was attempted. The results of the three successful tests are presented below.

TABLE 3. Adherency - Mepilex Transfer SID 50450

Dressing Type	Sample Number	Average peeling strength (N)	Average peeling strength (N/mm)
Mepilex Transfer	1	0.1272	0.0051
	2	0.2261	0.0090
	3	0.0376	0.0015
Mean		0.1303	0.0052
S.D.		0.094	0.004

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APPROVED:



Peter Phillips, Director, SMTL.

Date

21/11/16

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